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The Department of Vermont Health Access Medical Policy

Subject: Cystic Fibrosis Gene Test
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Revision 3:
Revision 2:
Revision 1:
Original Effective: June 15, 2015

Description of Service or Procedure

Cystic fibrosis (CF) is an autosomal recessive disorder (i.e. an individual needs to inherit a copy of a genetic variant from each parent in order to have the disease). If an individual inherits only one copy she will not inherit the actual disease but will be a carrier and could pass the disease to her children. If both parents carry the defective gene for CF, there is a 25% chance of producing a child with CF, a 50% chance the child will carry the CF gene but not have CF and a 25% chance the child will not carry the gene and not have CF. Approximately 70,000 individuals are affected by CF worldwide.

The CF gene test uses a blood sample or cells from inside the cheek for DNA analysis to identify the presence of a genetically altered cystic fibrosis transmembrane conductance regulator gene.

Prevalence of CF varies by ethnicity with Caucasians having the highest rates of about 1 in every 3,000 births.

Newborn screening for CF is done in the first 2 or 3 days after birth. If screening is positive, a sweat test is performed to confirm the diagnosis.

The severity of clinical symptoms that may occur in individuals with CF cannot be definitively predicted on cystic fibrosis transmembrane conductance regulator gene variant testing alone.

Genetic testing for CF is not available for the general public.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule that pertains to the beneficiary's aid category. Prior Authorization (PA) is only valid if the beneficiary is eligible for the applicable item or service on the date of service.

Medicaid Rule

7102.2 Prior Authorization Determination

7103 Medical Necessity

Medicaid Rules can be found at http://humanservices.vermont.gov/on-line-rules

Coverage Position

Cystic fibrosis testing may be covered for beneficiaries:

- When the CF gene test is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice in accordance with Vermont State Practice Act, who is knowledgeable in the use of the CF gene test and who provides medical care to the beneficiary AND
- When the clinical guidelines below are met.

Coverage Criteria

Cystic fibrosis testing may be covered for beneficiaries who:

1. Have clinical symptoms characteristic of CF (pancreatic insufficiency, lung function abnormalities and high sweat chloride test)
2. Have a family history of CF
3. Are couples planning a pregnancy
4. Are couples seeking prenatal care
5. Are reproductive partners of persons with CF
6. Desire a prenatal diagnosis to identify a fetus or embryo with CF for purposes of post-delivery care of the newborn.

Clinical guidelines for repeat service or procedure

The same criteria apply as for the initial use.

Type of service or procedure not covered (this list may not be all inclusive)

Cystic fibrosis testing for the general public is not covered.

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